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Abilify

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ABILIFY®

(aripiprazole) Tablets

Patient Information >>

WARNING

INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDAL THOUGHTS AND BEHAVIORS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some

Psoriasis

Symptoms, Causes and Treatment



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characteristic(s) of the patients is not clear. ABILIFY (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis [see WARNINGS AND PRECAUTIONS].

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of adjunctive ABILIFY or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. ABILIFY is not approved for use in pediatric patients with depression [see WARNINGS AND PRECAUTIONS].

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DRUG DESCRIPTION

Aripiprazole is a [psychotropic drug](#) that is available as ABILIFY®(aripiprazole) Tablets, ABILIFY DISCMELT®(aripiprazole) Orally Disintegrating Tablets, ABILIFY®(aripiprazole) Oral Solution, and ABILIFY®(aripiprazole) Injection, a solution for [intramuscular](#) injection. Aripiprazole is 7-[4-[4-(2,3-dichlorophenyl)-1piperazinyl]butoxy]-3,4-dihydrocarbostyryl. The empirical formula is C₂₃H₂₇Cl₂N₃O₂ and its molecular weight is 448.38. The chemical structure is:

VIEW ILLUSTRATION

ABILIFY Tablets are available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths. Inactive ingredients include cornstarch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. Colorants include ferric oxide (yellow or red) and FD&C Blue No. 2 Aluminum Lake.

ABILIFY DISCMELT Orally Disintegrating Tablets are available in 10 mg and 15 mg strengths. Inactive ingredients include acesulfame [potassium](#), [aspartame](#), calcium silicate, croscarmellose sodium, crospovidone, crème de vanilla (natural and artificial flavors), magnesium stearate, microcrystalline cellulose, silicon dioxide, tartaric acid, and [xylitol](#). Colorants include ferric oxide (yellow or red) and FD&C Blue No. 2 Aluminum Lake.

ABILIFY Oral Solution is a clear, colorless to light-yellow solution available in a concentration of 1 mg/mL. The inactive ingredients for this solution include disodium edetate, [fructose](#), glycerin, dl-lactic acid, methylparaben, propylene glycol, propylparaben, sodium hydroxide, sucrose, and purified water. The oral solution is flavored with natural orange cream and other natural flavors.

ABILIFY Injection is available in single-dose vials as a ready-to-use, 9.75 mg/1.3 mL (7.5 mg/mL) clear, colorless, sterile, aqueous solution for intramuscular use only. Inactive ingredients for this solution include 150 mg/mL of sulfobutylether β-cyclodextrin (SBECD), tartaric acid, sodium hydroxide, and water for injection.

for patients



What are the possible side effects of aripiprazole (Abilify,

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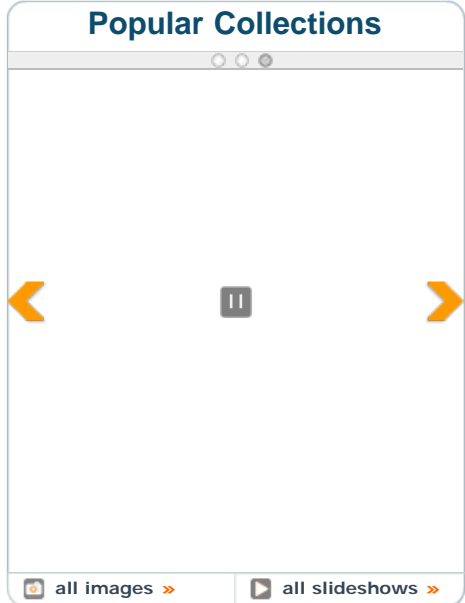
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Abilify Discmelt)?

Get emergency medical help if you have any of these **signs of an allergic reaction**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Stop using aripiprazole and call your doctor at once if you have a serious side effect such as:

- fever, stiff muscles, confusion, sweating, fast or uneven heartbeats;
- jerky muscle movements you cannot control;
- sudden numbness or weakness, headache, confusion, or problems with vision, speech, or balance;
- fever, chills, body aches, flu symptoms, sores in your mouth and...

[Read All Potential Side Effects and See Pictures of Abilify »](#)

What are the precautions when taking aripiprazole (Abilify)?

See also Warning section.

Before taking aripiprazole, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients (such as propylene glycol), which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: problems with blood flow in the brain (such as cerebrovascular disease, stroke), diabetes (including family history), heart problems (such as low blood pressure, coronary artery disease, heart failure, irregular heartbeat), nervous system problems (such as dementia, NMS, seizures), obesity, low white blood cell count (including history of low white blood cell count...

[Read All Potential Precautions of Abilify »](#)

Last reviewed on RxList: 6/19/2014

This monograph has been modified to include the generic and brand name in many instances.

Next: [Indications & Dosage](#)

Abilify FDA Prescribing Information

- Drug Description
- Overdosage & Contraindications
- Indications & Dosage
- Clinical Pharmacology
- Side Effects & Drug Interactions
- Medication Guide
- Warnings & Precautions

Additional Abilify Information

- Abilify Drug Interactions Center: [aripiprazole oral](#)
- [Abilify Side Effects Center](#)
- [Abilify in detail including Side Effects and Drug Images](#)
- [Abilify Overview including Precautions](#)
- [Abilify FDA Approved Prescribing Information including Dosage](#)

Abilify - User Reviews

Abilify User Reviews

Now you can gain knowledge and insight about a drug treatment with Patient Discussions.

[Here is a collection of user reviews for the medication Abilify sorted](#)

"Jan. 7, 2011 -- Many people taking powerful psychiatric medications that increase their risk of weight gain and diabetes are prescribed those drugs when there's little evidence that they will get any benefit from them, a new study shows.

"...

[Read the Study: Newer Antipsychotic Drugs Are Overused article »](#)

by most helpful. 

[See User Reviews](#)

Report Problems to the Food and Drug Administration



You are encouraged to report negative side effects of prescription drugs to the FDA. Visit the [FDA MedWatch](#) website or call 1-800-FDA-1088.



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